# Independent Review Board

STATE OF WISCONSIN

## MINUTES OF THE MEETING OF SEPTEMBER 17, 2004

**Attendance**

**Board Members:** Chair Dr. Jay Gold; Vice-Chair Dr. Paul Millea; Eileen Mallow; Jerry Popowski; and Dr. David Zimmerman.

**Bureau of Health Information and Policy Staff:** Susan Wood, Director; Judith Nugent, Chief, Health Care Information Section; Audrey Nohel; Wen-Jan Tuan; and Al Nettleton.

**Other Staff from the Department of Health and Family Services:** David Woldseth, Bureau of Managed Health Care Programs.

**Others Present:** Cindy Helstad, Wisconsin Medical Society; John Bott, Alliance Health Cooperative; Julie Coleman and Kathleen Janquart, Group Health Cooperative; and Robert Stone Newsom, Wisconsin Public Health Policy Institute.

**Call to Order**

At 2:02 p.m., Dr. Jay Gold called the meeting to order. A quorum was deemed present.

**Minutes of the July 16, 2004 meeting**

Dr. Zimmerman made a motion to approve the minutes, and Jerry Popowski seconded the motion. The motion passed, and the minutes were approved.

**Meeting dates for the coming year**

Dr. Gold noted that the IRB had previously been scheduled to meet on November 19. Due to a conflict, he would like the date moved up to November 12. All other dates had been selected by staff as the third Friday of each odd-numbered month. Without objection, the schedule for 2005 was adopted.

**Discussion and vote on the release of physician identifiers**

Dr. Gold stated that the IRB heard thoughtful presentations at the last meeting; however, the IRB itself did not have time to discuss the issue. Dr. Gold asked whether there was a possibility to phase in a new policy rather than simply choose to release. Judith Nugent told IRB members they have three choices: release as part of the public use data set, release as part of customized data sets, or choose not to release identifiers at all. She added that the IRB could choose to reverse course in the future.

Dr. Gold asked individual members for their opinions.

Jerry Popowski asked what the utility would be from release in the public use data set. Ms. Nugent stated that DHFS would set a fixed price, so it could be ostensibly less expensive for users that way. She added that regardless of whether or not the dataset is customized, users would need to fill out data use agreements and pay fees, and Attachment 3 covers some of those issues. Mr. Popowski said he prefers release with custom data requests. The IRB would then know how the data were being used. Therefore, he would favor a phased-in, gradual process. He said the data may not be perfect, but the project does have value. He asked Ms. Nugent whether DHFS knows how their data is used currently, and she said it was mainly hearsay. With customized data release, it differs somewhat

since the user is asked upfront what use is planned. Dr. Zimmerman asked if there were any consequences to data users for exceeding their stated purposes; Ms. Nugent informed him that DHFS does not fill their future requests when they violate their agreements.

Dr. Millea stated his opposition to release across the board. He questioned some of the technical elements and he also lamented the lack of risk adjustment to the data when such adjustment is necessary. Some diagnoses tend to be purer than others are, and when a patient has a number of symptoms, the value of the data decreases. People then make decisions or report conclusions based on faulty data.

Eileen Mallow expressed concerns about whether the data is ready for public use data release. She expressed concerns over possible misuse of the data, especially in regard to legal proceedings and malpractice cases.

Dr. Zimmerman said that release is the next logical step in the POV data process. The IRB has been moving in this direction for quite some time. He acknowledged that the data can be misused and abused. He also sees the litigation problems. Therefore, the IRB should move slowly, but potential misuse should not be an obstacle to moving forward. Dr. Zimmerman talked about a current perceived penalty for compliance because only Phase I submitters have information available to the public. That speaks to the need to move to Phases II and III quickly. Expeditious movement through the next two phases will provide information more rapidly to the public. Dr. Zimmerman would like stronger penalties for misuse of the data, and he would like continued work in the area of risk adjustment. Ms. Nugent stated that statutes call for jail time if necessary if data are misused.

Dr. Gold closed the discussion by stating that, if it were an "all or nothing" endeavor, he would vote for "all." The benefits seem certain and the risks only potential. However, the IRB does have the option to phase in release. Therefore, he would recommend that the IRB not include the identifiers in the public use data set at this time, and, as customized requests come in, the IRB can see if fears are realized.

Judith Nugent would like to start advertising the data, so that more requests will be submitted, and a "case law" can be developed. Ms. Mallow made a motion to request she do that. Seconded by Dr. Zimmerman, the motion passed unanimously.

Dr. Zimmerman would like the IRB to revisit the subject of public use data release after IRB has several months of experience. He would like this added to the agenda in six to nine months to make sure the IRB discusses its experience.

Dr. Millea wants the IRB to retain the right to look at how the data are being used. He cautioned that the release of physician identifiers may change behavior since behavior changes when there is surveillance, and doctors would be no different. The release may also change the power relationship between doctors and attorneys and/or the insurance industry. This may conflict with a patient's best interest.

Mr. Popowski moved, and Dr. Zimmerman seconded the motion, that the IRB:

- Will not permit release of physician identifiers in the public use data set;
- Will seek reasonable requests for customized data sets that may include physician identifiers;
- Will review this decision at their March 18, 2005, meeting; and
- Will consider release of physician identifiers in the public use data set at that time.

The motion carried unanimously.

**UW-Madison request for data on patterns of colorectal cancer screening in Wisconsin**

Judith Nugent distributed a data request from UW-Madison. Dr. Robert Newsom, one of the

researchers who submitted the request, was present, and he said he would like to proceed as soon as possible. The IRB decided to consider his request immediately.

Dr. Newsom brought to the IRB's attention points nine and ten in the proposal, which specifically delineated how the POV data would be used.

Eileen Mallow asked if this would involve numbers rather than names. Ms. Nugent said that would not be the case. Dr. Newsom explained that the researchers need the license numbers in order to link to information about the physician's education and training. Ms. Nugent said this was the only way to link the data. Dr. Zimmerman said the researchers have no intent to publicize the names. They will be looking at variation around the state and having real numbers will be more helpful than creating proxy numbers.

Dr. Gold asked if there would be any repercussions from approving this study. Dr. Millea referenced a recent journal article that addressed similar issues and proved not to be a convincing study since the data lacked risk adjustment.

Dr. Gold pointed out that the University's Institutional Review Board had already approved this study. Presumably, they have taken these issues into account. Nevertheless, Dr. Millea stated there was public risk to consider and asked the larger question of what the role of the IRB was—to release data or also to review studies?

Dr. Newsom told IRB that the UW was paying for the study rather than another entity financing it. Dr. Zimmerman stated that because this was self-funded rather than NIH-funded, the IRB would need to give it additional consideration. If the study becomes larger than the one presented today, Dr. Newsom is aware that he will need to return and ask for the IRB's approval of the expanded study.

Jerry Popowski made a motion to approve the UW request; Dr. Gold seconded. The motion carried unanimously.

**Presentation on the data request tracking system**

Audrey Nohel distributed a handout entitled, "Custom Data Request Process: An Overview." Her team has been planning a process to review customized data requests. Ms. Nohel distributed a flowchart that describes the project. Dr. Zimmerman asked how requests would be distributed to IRB members; due to privacy concerns, data cannot be provided with meeting packets. Instead, descriptions must be given since administrative rules prescribe what must be in a sample packet and how privacy is protected. Requesters will be asked to document their requests and pre-pay, although prices have not yet been set for customized data requests. Each user must sign a data use agreement that is good for one year.

A few questions do linger. First, who will sign the approved requests? Second, who will sign the rejected requests? Dr. Gold said the IRB chair probably should sign them, and Ms. Nugent promised to get back to the group on that question. Dr. Newsom asked if there was redress for rejections, and Ms. Nohel said there would be since the IRB can reject but can also request modifications. Ms. Mallow stated applicants should be invited to the meetings in order to answer questions when posed.

Although the IRB approved a request today, this was not a model request. The process described by Ms. Nohel would be the model process. The UW request derived from a specific request by the DHFS Secretary's office.

**Report on the August 3 Board on Health Care Information meeting**

Judith Nugent reported the BHCI failed to make quorum August 3. Meeting as a committee of the whole, members discussed a number of subjects. These topics included the reorganization of the Division of Public Health, the powers and duties of BHCI, the new Public Health Council, the privatization of data collection, POV data, and future agenda items.

**Potential items for upcoming IRB meeting**

- Data requests that may arise due to the energized efforts to find data requesters;
- Bylaws changes dictated by the reorganization of the Bureau of Health Information and Policy; and
- Report on the October 5 meeting of the Board on Health Care Information.

**Next IRB meeting**

The next meeting has been scheduled for November 12, 2004, 10:00 a.m. to 12:00 p.m., at the State Office Building, One West Wilson Street, Conference Room 372, Madison, Wisconsin.

**Adjournment**

Dr. Gold adjourned the meeting at 3:48 p.m.